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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,015	11/28/2001	Kerry E. Quinn	15966-581CIP (Cura-81 CIP	2939
7590	06/23/2004		EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY and POPEO, P.C. One Financial Center Boston, MA 02111			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/996,015

**Applicant(s)**

QUINN ET AL.

**Examiner**

Delia M. Ramirez

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 1-43 are pending.

It is noted that claims 35-37 are directed to a use, which is non-statutory matter, i.e. not a product or a method. For restriction purposes, it will be assumed that the term recited "the use of a therapeutic in the manufacture" will be interpreted as "a method to manufacture a therapeutic". Applicants are requested to amend these claims in response to this Office Action if they are part of the elected invention.

Claim 28 is directed to the method of claim 15. However claim 15 is directed to an antibody. For restriction purposes, it will be assumed that claim 28 is directed to the method of claim 27. Applicants are requested to amend these claims in response to this Office Action if they are part of the elected invention.

Claim 39 is directed to the method of claim 36 further limiting a test animal. However, claim 36 does not refer to a test animal. For restriction purposes, it will be assumed that claim 29 is directed to the method of claim 38. Applicants are requested to amend these claims in response to this Office Action if they are part of the elected invention.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1-4, 29, 32, drawn in part to a polypeptide comprising SEQ ID NO: 2, 6 or 8, respectively, classified in class 435, subclass 212 (i.e. Group I is directed to the polypeptide of SEQ ID NO: 2, Group II is directed to the polypeptide of SEQ ID NO: 6, and Group III is directed to the polypeptide of SEQ ID NO: 8).

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- IV-VI. Claims 5-14, 30, 33, drawn in part to a polynucleotide encoding the polypeptide of SEQ ID NO: 2, 6 or 8, respectively, classified in class 536, subclass 23.2.
- VII-IX. Claims 15-17, 31, 34, drawn in part to an antibody which binds to a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 530, subclass 387.1.
- X-XII. Claim 18, drawn in part to a method for determining the presence or amount of a polypeptide using an antibody which binds to a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 436, subclass 512.
- XIII-XV. Claim 19, drawn in part to a method for determining the presence or amount of a polynucleotide by using a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 436, subclass 94.
- XVI-XVIII. Claim 20, drawn in part to a method for identifying an agent which binds to a polypeptide by using a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 436, subclass 86.
- XIX-XXI. Claim 21, drawn in part to a method for identifying a potential therapeutic agent using a cell comprising a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 6 or 8, respectively, classified in class 436, subclass 94.
- XXII-XXIV. Claim 22, drawn in part to a method for modulating the activity of a polypeptide using a cell comprising a polynucleotide encoding a

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polypeptide comprising SEQ ID NO: 2, 6 or 8, respectively, classified in class 435, subclass 325.

XXV-XXVII. Claims 23-24, 42, drawn in part to a method of treating or preventing a pathology by administering a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 424, subclass 94.63.

XXVIII-XXX. Claims 25-26, drawn in part to a method of treating or preventing a pathology by administering a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 514, subclass 44.

XXXI-XXXIII. Claims 27-28, 43, drawn in part to a method of treating or preventing a pathology by administering an antibody which binds to a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 424, subclass 130.1.

XXXIV-XXXVI. Claim 35, drawn in part to a method to manufacture a therapeutic containing a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 424, subclass 94.63.

XXXVII-XXXIX. Claim 36, drawn in part to a method to manufacture a therapeutic containing a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 514, subclass 44.

XL-XLII. Claim 37, drawn in part to a method to manufacture a therapeutic containing an antibody which binds to a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 424, subclass 130.1.

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- XLIII-XLV. Claims 38-39, drawn in part to a method for screening for a modulator of activity using a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 435, subclass 24.
- XLVI-XLVIII. Claim 40, drawn in part to a method for determining the presence of or predisposition to a disease using a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 436, subclass 86.
- XLIX-LI. Claim 41, drawn in part to a method for determining the presence of or predisposition to a disease using a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 6, or 8, respectively, classified in class 436, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IX each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The polynucleotides in Groups IV-VI each comprises an unrelated nucleic acid sequence, whereas the proteins of Groups I-III and VII-IX each comprise an unrelated amino acid sequence. The polynucleotides have other uses besides encoding the proteins of Groups I-III, such as a hybridization probe or in gene therapy. The protein from Groups I-III can be used in materially different methods other than to make the antibody of Groups VII-IX, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the proteins of Groups I-III can be prepared by processes which are materially different from recombinant expression of the polynucleotides of Groups IV-VI, such as by chemical synthesis, or by isolation and purification from natural sources. The polynucleotides of Groups IV-VI cannot be used to manufacture the antibodies of Groups VII-IX.
3. Inventions I-III, XVI-XVIII, XXV-XXVII, XXXIV-XXXVI, XLIII-XLV and XLVI-XLVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the

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following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Inventions I-III can be used in the distinct methods of Inventions XVI-XVIII, XXV-XXVII, XXXIV-XXXVI, XLIII-XLV and XLVI-XLVIII, as well as in eliciting the antibodies of Inventions VII-IX.

4. Inventions IV-VI, XIII-XV, XIX-XXIV, XXVIII-XXX, XXXVII-XXXIX, and XLIX-LI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Inventions IV-VI can be used in the distinct methods of Inventions XIII-XV, XIX-XXIV, XXVIII-XXX, XXXVII-XXXIX, and XLIX-LI as well as in the recombinant production of the polypeptides of Inventions I-III.

5. Inventions VII-IX, X-XII and XXXI-XXXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Inventions VII-IX can be used in the distinct methods of Inventions X-XII and XXXI-XXXIII, as well as in the purification of the proteins of Groups I-III.

6. Inventions IV-IX, XVI-XVIII, XXV-XXVII, XXXIV-XXXVI, XLIII-XLV and XLVI-XLVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides and antibodies of Inventions IV-IX are neither used nor made by the methods of Inventions XVI-XVIII, XXV-XXVII, XXXIV-XXXVI, XLIII-XLV or XLVI-XLVIII.

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7. Inventions I-III, VII-IX, XIII-XV, XIX-XXIV, XXVIII-XXX, XXXVII-XXXIX, and XLIX-LI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides and antibodies of Inventions I-III and VII-IX are neither used nor made by the methods of Inventions XIII-XV, XIX-XXIV, XXVIII-XXX, XXXVII-XXXIX or XLIX-LI.

8. Inventions I-VI, X-XII and XXXI-XXXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides and polynucleotides of Inventions I-VI are neither made nor used by the methods of Inventions X-XII or XXXI-XXXIII.

9. Inventions X-LI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions X-LI have different steps, may use different products and produce different results.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments

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submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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15. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
June 10, 2004

  
PONNATHAPU ACHUTAMURTHY  
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